HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

June 3, 1999

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

Dear Sir or Madam:

The undersigned, on behalf of the Health Industry Manufacturers Association's (HIMA) In Vitro Diagnostics Task Force, submits this Petition to the Food and Drug Administration (FDA) pursuant to § 553(e) of the Administrative Procedure Act (APA),[1] 21 CFR 10.30, and to 21 CFR 801.437(i). HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA's members manufacture nearly 90 percent of the $58 billion of health care technology products purchased annually around the world.

I. ACTION REQUESTED

HIMA submits this Petition to request that FDA grant a general variance from the labeling regulation for natural rubber latex -containing medical devices, 21 CFR 801.437(i), that will allow manufacturers to omit the warning statement "This product contains Dry Natural Rubber," from the product label affixed to the vials of in vitro diagnostic (IVD) products. The variance would apply to IVD products when the vial label is too small to accommodate this required warning statement and there is an outer container and a product insert that can accommodate this warning statement.

1 Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified at 5 USC §§ 551 et seq.).

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99P-1720

CP1

II. STATEMENT OF GROUNDS

This request is based is based on the following:

1. Vial labels are too small to accommodate the required warning statement.

   The final rule for natural rubber latex containing medical devices requires manufacturers to declare the presence of natural rubber latex on all device labels including "the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container or wrapper," 21 CFR 801.437(e). Since FDA's main goal is to notify users of the presence of natural rubber latex, those users will be provided adequate notification of the presence of natural rubber latex via a warning printed on the outer container and product insert. This is consistent with the regulations governing IVD labeling that allow warnings and precautions to appear on the outside container or wrapper rather than on the immediate container label when the IVD product label is too small to accommodate required warnings and precautions. (21 CFR 809.10(a)(10)).

2. This request is consistent with the variance granted by FDA to Bio-Rad on March 24, 1999 (copy attached).

   In its March 24, 1999 response to Bio-Rad's request for a variance, FDA acknowledged the following:

   > "The labeling variance you [Bio-Rad] proposed conforms to the precedent established by the agency under the general labeling requirements for in vitro diagnostic products under 21 CFR 809.10, and the agency's treatment of warnings for reagent package inserts. Accordingly, the agency will not consider your in vitro diagnostic product misbranded by omitting the natural rubber warning information from the immediate container provided this information appears on the outer package and the package insert . . ."

HIMA believes that by granting a general variance and thus expanding the variance granted to Bio-Rad to include other companies similarly situated in the IVD industry, FDA and industry resources can be conserved. Granting a general variance will avoid the need for FDA to review and respond to individual variance requests from every company in the IVD industry.

III. ENVIRONMENTAL IMPACT

The action requested in the Petition has no significant environmental impacts and is categorically exempt from the environmental assessment requirement under 21 CFR 24.14(c)(10).

IV. ECONOMIC IMPACT

Information on the economic impact of the action requested in this Petition will be submitted upon request of the Commissioner.

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner, which are unfavorable to the Petition.

Sincerely,

Carolyn D. Jones

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cc: Lillian Gill, FDA
Linda Kahan, FDA
Joseph Sheehan, FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 24 1999

Ms. Elizabeth Platt
Regulatory Affairs Representative
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, California 92618

Re: Docket #98P-0659/CP 1

Dear Ms. Platt:

This is in response to your petition dated July 31, 1998, requesting two variances from the requirements of the labeling regulation for natural rubber-containing medical devices; incorporated in 21 Code of Federal Regulations (CFR) 801.437, which became effective September 30, 1998. We apologize for the delay in responding to you.

First, your petition requested that Bio-Rad be allowed to omit the statement "This product contains Dry Natural Rubber," from the product label affixed to the vials of your in vitro diagnostic products. The basis for this request is that the vial label is too small to present additional labeling that would be legible, and that the availability of the required information on the outer package as well as in the package insert sufficiently informs the user of the hazard. Second, you proposed that for products manufactured before September 30, 1998, Bio-Rad be allowed to provide the required information on stickers affixed to the outer package and in a supplemental package insert placed inside the package.

The agency is hereby granting your first request to omit the natural rubber information from the vial's immediate label and to provide the information elsewhere on the outer package and in the package insert.

As you know, the final rule for natural rubber containing devices (21 CFR 801.437) requires you declare the presence of natural rubber on all device labels, other labeling, the principal display panel of the device packaging, the outside-package, container or wrapper, and the immediate device package, container, or wrapper. Despite this approach to ensure complete labeling, the agency recognizes that some immediate containers, such as your product's vials, are too small or otherwise unable to accommodate a label with sufficient space to bear all such information and the vials are packaged in an outer container.

The regulation covering labeling for in-vitro diagnostic products allows these products to bear statements of warnings and precautions on the outer container labeling when the immediate containers are too small or otherwise unable to accommodate the warnings (21 CFR 809.10(a)(10)). Such warnings are also required on the package inserts of

diagnostic products. Therefore, the agency has routinely allowed required warnings to be listed on the outer package and the package insert of in vitro diagnostic products, as appropriate to the hazard presented by the product.

The labeling variance you have proposed conforms to the precedent established by the agency under the general labeling requirements for in vitro diagnostic products, under 21 CFR 809.10, and the agency's treatment of warnings for reagents in package inserts. Accordingly, the agency will not consider your in vitro diagnostic product misbranded by omitting the natural rubber warning information from the immediate container provided this information appears on the outer package and the package insert, and provided the information otherwise conforms with the requirements of 21 CFR 801.437.

The agency is also granting your request for a second variance, which is to provide the required information on stickers affixed to the outer package and in a supplemental package insert placed inside the package for in vitro diagnostic products manufactured before September 30, 1998, but distributed after that date. The final rule allows the use of stickers in supplementary labeling to provide the required labeling information. This will avoid extensive repackaging of existing product inventory that will not be sold prior to the implementation period.

The agency welcomes your effort to implement the new labeling requirements by the effective date of the final rule. We understand, however, that some manufacturers may have assumed that their in vitro diagnostic products were not covered by the final rule. Consequently, they had not completed the steps necessary for relabeling products by September 30, 1998. As a result, the agency intends to exercise its enforcement discretion by suspending regulatory action for failure to provide natural rubber labeling information provided manufacturers are in full compliance with labeling requirements as of September 26, 1999.

I hope this response has been helpful

Sincerely yours,

Linda D. Kahan for

Elizabeth D. Jacobson, Ph.D.
Acting Director
Center for Devices and
Radiological Health